

REMARKS

This Response is submitted in response to the non-final Office Action mailed on August 11, 2005. Claims 8-20 are pending in this application. In the Office Action, Claims 8-20 are rejected under 35 U.S.C. §103 and Claims 8-20 are rejected under double patenting. In view of the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 8-20 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,578,336 to Monte (“*Monte*”). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claims 8 and 16 recite, in part, a coating comprising a medicament and the coating comprising at least 50% by weight of the product. Applicants respectfully submit that all of the claimed elements are not taught or suggested by *Monte*. For example, in contrast to the present claims, *Monte* fails to disclose or suggest a coating comprising at least 50% by weight of the product. Instead, *Monte* only discloses that its product has coating layers. See, *Monte*, column 2, lines 62-67.

Applicants respectfully disagree with the Patent Office’s assertions that the claimed coating limitations are not entitled to any patentable weight. The claimed coating levels are not conventionally used in the confectionery industry, and thus, these levels would not be obvious. *Monte* fails to even suggest a product having at least 50% by weight of a coating as required by Claims 8 and 16. In fact, *Monte* fails to suggest the problems that Applicants’ invention seeks to overcome. Regardless, Applicants have demonstrated the importance of the claimed coating levels.

Applicants have surprisingly found that administering medicament through chewing, as opposed to swallowing, results in faster drug absorption through the oral mucosa. In this manner, an increase in the absorption of the medicament is achieved as well as an increase in the bioavailability of the drug as compared to typical oral administration. Indeed, the absorption approaches that of a parenteral administration, and the bioavailability is also much greater than oral administration.

Conventional consumable centers do not contain a significant amount of coating by weight of the product. As a result, in order to create a consumable center with a sufficient amount of medicament in a coating, certain levels of coating must be present in each consumable

product to achieve the desired effect. By using such a high coating level, the level of medicament or agent in the coating can be selected so as to create, when the product is chewed, a sufficiently high concentration of the medicament or agent in the saliva. On the other hand, *Monte* fails to teach or recognize the need to deliver medicaments through the oral mucosa and therefore does not need its product to have at least 50% by weight of a coating as required by the present claims.

Applicants have discovered the novel way of delivering medicaments to an individual through the oral mucosa by using a consumable center having a medicament in a coating. The high coating level allows a sufficient amount of medicament to be delivered to a consumer, for example, to maintain the medicament in his mouth for a sufficient time to allow as much of the medicament into the saliva. The medicament in the saliva can then pass more readily through the oral mucosa in the buccal cavity, which favors faster drug absorption over oral ingestion. Applicants have carefully researched the desirability, applicability and levels of the coating and medicament for such oral administration. Again, nowhere does *Monte* recognize or successfully employ the benefits of medicament absorption through the oral mucosa.

For the reasons discussed above, the *Monte* does not teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 8-20 be reconsidered and the rejection be withdrawn.

In the Office Action, Claims 8-20 have been rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of Claims 8-15 and 36-48 of U.S. Patent Application No. 10/206,492. Applicants respectfully submit that Claims 8 and 16 in this application which currently requires “a consumable center” are patentably distinct from Claim 8 in Application No. 10/206,492 which now requires “a tableted center comprising at least one compressible saccharide or sugar alcohol.” For example, these limitations are clearly distinguishable because a consumable center need not necessarily comprise “a compressible saccharide or sugar alcohol.” Likewise, Claims 8 and 16 are patentably distinct from independent Claim 36 of the 10/206,492 application which currently requires “a center comprising at least one saccharide or sugar alcohol” because consumable centers need not contain saccharides or sugar alcohols. Similarly, Claims 8 and 16 are distinct from independent Claim 44 of the 10/206,492 application which

currently requires "a center that is defined by at least one excipient" because consumable centers need not contain excipients. In view of the distinctions between the independent claims of the two applications, Applicants respectfully submit that Claims 8-20 do not claim the same invention as Claims 8-15 and 36-48 of U.S. Patent Application No. 10/206,492.

Accordingly, Applicants respectfully request that the double patenting rejection of Claims 8-20 under 35 U.S.C. §101 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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